

Introduced by Senator Hill

January 6, 2014

An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as introduced, Hill. Food-producing animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that food products are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, for use on a food-producing animal, unless prescribed requirements are met. The bill would provide that a medically important antimicrobial drug currently registered with the department that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would require a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug. Because a violation of the bill's provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 14288 of the Food and Agricultural Code
2 is amended to read:

3 14288. The ~~director~~ *secretary* shall refuse to register a livestock
4 drug if he *or she* finds any of the following is true of the drug:

5 (a) It is of little or no value for the purpose for which it is
6 intended to be used.

7 (b) It is dangerous to the health of livestock if used in accordance
8 with the instructions.

9 (c) The instructions for use do not contain adequate warnings
10 against use in those conditions, whether pathological or normal,
11 under which its use may be dangerous to the health of livestock
12 or humans who consume products from ~~such~~ *the* livestock, or
13 against unsafe dosage, unsafe duration of use, or unsafe methods
14 of administration.

15 (d) If the application and the accompanying material, data, and
16 information do not comply with the requirements of this chapter
17 or are insufficient to permit the ~~director~~ *secretary* to make the
18 determinations ~~which~~ *that* are required by this section.

19 (e) *It is a medically important antimicrobial drug, as defined*
20 *in Section 18770, for use in food-producing animals, unless the*
21 *drug complies with Section 18771.*

22 SEC. 2. Article 4.5 (commencing with Section 18770) is added
23 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural
24 Code, to read:

25
26 Article 4.5. Medically Important Antimicrobial Drugs
27

28 18770. For purposes of this article, the following definitions
29 apply:

30 (a) “FDA” means the federal Food and Drug Administration.

31 (b) “Medically important antimicrobial drug” means an
32 antimicrobial drug listed in Appendix A of the FDA Guidance for
33 Industry #152, including a critically important, highly important,

1 and important antimicrobial drug. The secretary may determine
2 that any updates to this list by the FDA are also medically
3 important antimicrobial drugs.

4 18771. To comply with FDA Guidance for Industry #213,
5 dated December 2013, a medically important antimicrobial drug,
6 including a combination drug incorporating a medically important
7 anti microbial drug, shall meet all of the requirements in the
8 guidance document, including, but not limited to, the following:

9 (a) To reflect the need for professional oversight by a licensed
10 veterinarian, the manufacturer shall remove from the approved
11 production uses on the label of the medically important
12 antimicrobial drug or combination drug the production indications,
13 including, but not limited to, “increased rate of weight gain” or
14 “improved feed efficiency.”

15 (b) The manufacturer shall revise the condition of the use of the
16 medically important antimicrobial drug or combination drug from
17 over the counter availability to a marketing status requiring
18 veterinary prescription, including, but not limited to, the following:

19 (1) For medicated feed products, a change from over the counter
20 to veterinary feed directive.

21 (2) For medicated drinking water products, a change from over
22 the counter to veterinary prescription.

23 (c) The medically important antimicrobial drug may only be
24 used to treat, prevent, or control disease under the supervision of,
25 or by prescription from, a licensed veterinarian.

26 18772. There shall be a veterinarian-client-patient relationship
27 to ensure that a medically important antimicrobial drug is used in
28 a manner that is consistent with professionally accepted best
29 practices. For the purposes of this section, a
30 “veterinarian-client-patient relationship” is a relationship meeting
31 the requirements of Section 2032.1 of Title 16 of the California
32 Code of Regulations.

33 18773. If a medically important antimicrobial drug, or
34 combination drug, for use in food-producing animals is registered
35 with the department as of January 1, 2015, and the drug does not
36 comply with Section 18771, the manufacturer of the medically
37 important antimicrobial drug, or combination drug, shall have until
38 January 1, 2017, to reregister the drug with the secretary. The
39 secretary shall refuse to reregister the drug unless it complies with
40 Section 18771.

1 SEC. 3. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution because
3 the only costs that may be incurred by a local agency or school
4 district will be incurred because this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the penalty
6 for a crime or infraction, within the meaning of Section 17556 of
7 the Government Code, or changes the definition of a crime within
8 the meaning of Section 6 of Article XIII B of the California
9 Constitution.

O